## **REMARKS**

In the Office Action all pending claims were rejected under 35 U.S.C. 112, first paragraph, "because the specification, while being enabling for a composition for inducting immune response, does not reasonably provide enablement for vaccinating against HIV, as contemplated by the Applicants." As explained in the Office Action, "it is well know in the art of HIV infection, there is no vaccine that is available as of today." In order for the Applicants to claim such a vaccine, they must show credible data, without undue experimentation, to overcome skepticism within those skilled in the art.

Applicants respectfully submit that the rejection is improper for lack of enablement under 35 U.S.C. 112, first paragraph. In particular, the Office Action fails to provide any specifics regarding the lack of enablement rejection such as why one of ordinary skill in the art would not be able to carry out the invention as claimed.

Applicants assert that instead of a rejection for lack of enablement, the Office Action actually alleges that all claims are rejected under 35 U.S.C. 112, first paragraph based on a lack of utility (i.e., the asserted utility is not credible). See, MPEP §2107.01(IV). Accordingly, the Applicants will address the Office Action as if brought under this basis.

Applicants respectfully assert that a previous lack of success by others, "cannot serve as the basis for a conclusion that such an invention lacks utility." MPEP § 2107.03. Instead, a determination regarding if the asserted utility for the invention is credible must be based on the information disclosed in the application.

The Office must make a *prima facie* showing why the claimed invention lacks utility whenever a rejection is based on the lack of credibility of an asserted and substantial utility. This showing includes: "(a) an explanation that clearly sets forth the reasoning used in concluding that

the asserted specific and substantial utility is not credible; (b) support for factual findings relied upon in reaching this conclusion; and (c) an evaluation of all relevant evidence of record, including utilities taught in the closest prior art." MPEP § 2107.02(IV).

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn and all claims passed to issue because a prima facie showing why the claimed invention lacks utility has not be made. As stated, a previous lack of success by others, cannot serve as the basis for a conclusion that the claimed invention lacks utility.

Should anything further be required, a telephone call to the undersigned, at (312) 226-1818, is respectfully invited.

Respectfully submitted,

FACTOR & LAKE, LTD.

Dated: December 2, 2004

Jody L. Factor

One of Attorneys for Applicant

## **CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on December 2 \( \mathcal{V} \), 2004

Jody L. Factor

Name of Applicant, Assignee, Applicants Attorney or Registered Representative